IN THE

Supreme Court of the United States

OCTOBER TERM, 1975

No. 75-1199

CHRISTIAN J. JANSEN, JR.,
Petitioner,

vs.

C. MARSHALL DANN,
COMMISSIONER OF PATENTS AND TRADEMARKS,
Respondent.

PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF CUSTOMS AND PATENT APPEALS

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Petitioner, Christian J. Jansen, Jr., prays that a writ of certiorari issue to review the judgment of the United States Court of Customs and Patent Appeals entered November 20, 1975, a timely filed petition for rehearing being denied on January 15, 1976.

REFERENCE TO OPINIONS BELOW

The opinions of the United States Patent and Trademark Office Board of Appeals are not reported but are set forth in Appendix A, *infra* pp. A1-A10. The opinion of the United States Court of Customs and Patent Appeals is reported at 525 F.2d 1059, 187 USPQ 743 (1975) and is set forth in Appendix A, *infra* pp. A11-A17.

JURISDICTION

The judgment of the United States Court of Customs and Patent Appeals was dated November 20, 1975. A petition for rehearing was filed on December 9, 1975 and was denied on January 15, 1976.

The jurisdiction of this Court is invoked under the provisions of 28 U.S.C. § 1256.

CONSTITUTIONAL PROVISION AND STATUTE

The Constitutional provision involved is Article 1, Section 8, which reads as follows:

> "The Congress shall have power . . . To promote the progress of science and useful arts, by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries."

The Federal Statute involved is 35 U.S.C. § 103 which reads as follows:*

> "A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made."

QUESTIONS PRESENTED

1. Whether for a pharmaceutical product the standards of patentability under the Constitution and under 35 U.S.C.

* This same language is retained in proposed patent reform legislation such as Senate Bill S. 2255 which has received approval of the Senate Committee on the Judiciary.

§ 103 can be applied without consideration of significantly improved results obtained by a novel formulation.

2. Whether rejection of claims in a patent application relating to a pharmaceutical product can be made by the Patent and Trademark Office under 35 U.S.C. § 103 without challenge to applicant's position and evidence that the admittedly novel subject matter of the claims are substantial improvements over the prior art which eliminate risks of needless sickness and death and which reduce the cost of medical care inherent in each and every prior art product.

3. Whether a pharmaceutical product having demonstrably improved safety and which is formulated contrary to the teachings of persons of skill in the art is patentable under the Constitutional and statutory standards.

STATEMENT OF THE CASE

Christian J. Jansen, Jr. filed for a patent application on a vitamin formulation which preferably included the two vitamins, vitamin B_{12} and folic acid, each in the amount of .5 milligrams. The Patent Office denied a patent to Dr. Jansen based upon the provisions of 35 U.S.C. § 103.

Folic acid (pteroylglutamic acid) and vitamin B_{12} (cyanocobalamin) are both vitamins. Vitamins are nutrients which are needed in small amounts by all individuals throughout their entire lifetime. While a balanced diet will provide normal individuals with enough of each of these two vitamins, it is common practice for persons to take vitamin supplements to insure that they have the vitamins which they need in the event that they do not always eat a balanced diet.

The prior art is replete with vitamin supplement products containing both folic acid and vitamin B_{12}. How-

ever, the folic-acid-containing products of the prior art which contain enough folic acid to supply the recommended daily allowance are recognized as having dangers associated with them. The danger lies in the possibility that administration of these folic-acid-containing products to a person who happens also to be deficient in vitamin B_{12} causes masking to occur. Masking is the suppression of the anemic condition which otherwise would result from a vitamin B_{12} deficiency. Thus, the folic acid ameliorates the anemia caused by the vitamin B_{12} deficiency and the person appears cured. Thereafter, however, irreversible neurological damage occurs. The person may suddenly become crippled. The person may die.

Most folic acid containing products also contain small amounts of vitamin B_{12}. These small amounts of vitamin B_{12} are enough to insure that a *normal* individual will have sufficient vitamin B_{12} to avoid the problem of masking and to avoid the resultant problem of permanent neurological damage or death. However, a large number of individuals have or develop during their lifetimes a malfunction which prevents effective absorption of the small amounts of vitamin B_{12} which often accompany folic-acid-containing products. These persons are referred to as having pernicious anemia. For these individuals taking the folic-acid-containing products, permanent irreversible neurological damage can still occur even though small amounts of Vitamin B_{12} (.005 to .05 mg.) are present in the folic-acid-containing products. Death can occur. Products containing folic acid in substantial amounts are distributed only as prescription products which are available only with the direction of a physician. Folic-acid-containing products are often accompanied by warning labels warning of the dangers

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• Goodman & Gilman, *The Pharmacological Basis of Therapeutics*, 1440 (4th ed. 1970).

associated with the product. A medical textbook• makes the following statement:

> "It is therefore incumbent on the physician *never* to prescribe a multi-vitamin preparation containing more than .1 mg. of folic acid per daily dose unless he is reasonably sure that the patient does not have vitamin B_{12} deficiency."

The Food and Drug administration has regulations concerning the labeling with warning labels of preparations containing folic acid and cyanocobalamin. All prior art multi-vitamin products have either an insufficient amount of folic acid to provide the recommended daily allowances or have so much folic acid as to present a danger to those persons who have or may develop difficulties in absorbing vitamin B_{12}. The prior art does not offer any safe method or product whereby an individual can receive the amount of folic acid he needs in a vitamin supplement without taking a product which is potentially a dangerous product, requiring a physician's care.

It is at this defect in the prior art products that appellant's invention is directed. Appellant has discovered that if the amount of vitamin B_{12} contained with oral folic-acid-containing products is increased substantially over the amount previously present in oral folic-acid-containing products, that the folic acid can be delivered safely and without any risk of neurological damage or death. Careful clinical studies were run on over 100 individuals to verify the improved safety of Dr. Jansen's preparation. Evidence of this was submitted to the Patent and Trademark Office. Many of the persons participating in the study were known to have pernicious anemia. The novel folic-acid-containing formulation proved to be completely safe and effective even when given to persons who were vitamin B_{12} deficient and who had been proven to have difficulty in absorbing vita-

min B_{12}. The presence of large amounts of folic acid in the novel formulation did not result in any neurological damage or death which otherwise would have resulted if a prior art product containing large amounts of folic acid had alone been given.

For the first time a product was formulated which could be given to the general public to provide a safe and inexpensive way to insure that they had the nutrients they needed. For the first time a product was formulated which could be given to the general public to fully and safely prevent vitamin deficiency anemias in the same way that vitamin C is now used to prevent scurvy. Contrary to the situation existing in the prior art, a person taking the novel formulation does not need to first become ill with a vitamin deficiency and thereafter seek the help of a physician. Nor is it necessary with the novel formulation for a person to be tested with difficult, expensive and time consuming tests which would otherwise be necessary to differentiate between vitamin B_{12} deficiency and folic acid deficiency.

Dr. Jansen has been seeking permission from the Food and Drug Administration to market his improved formulation by filing a new drug application. When the FDA learned that the preparation of Dr. Jansen contained large quantities of folic acid, they responded saying that such amount is dangerous and its use should be carefully monitored. Marvin Seife, Acting Director of the Office of Scientific Evaluation of the Bureau of Drugs of the FDA, stated to Dr. Jansen that his views on the safety and efficacy of his proposed product were not shared by the preponderance of contemporary scientific-medical opinion. He went on to quote literature to support his position. Long after Dr. Jansen made his invention and filed for his patent application, companies have continued to manufacture and

sell folic-acid-containing products which admittedly had either insufficient amounts of folic acid to supply the recommended daily allowances for individuals or admittedly were dangerously formulated to result in possible masking of vitamin B_{12} deficiencies. Nonetheless there is not one person of record, other than Dr. Jansen, who has advocated use of the safe formulation of folic-acid-containing products discovered by Dr. Jansen.

JURISDICTION OF THE UNITED STATES COURT OF CUSTOMS AND PATENT APPEALS AND THE PATENT AND TRADEMARK OFFICE

The jurisdiction of the United States Court of Customs and Patent Appeals arose under 28 U.S.C. § 1542. The jurisdiction of the Patent and Trademark Office arose under Title 35, Parts I and II, of the United States Code, and more particularly under 35 U.S.C. § 131. Appeal from the decision of the Board of Appeals of the Patent and Trademark Office is provided for additionally by 35 U.S.C. § 141 through § 144. Christian J. Jansen, Jr. filed his application for a patent on July 22, 1970. The appeal to the United States Court of Customs and Patent Appeals was filed on December 11, 1974.

REASONS FOR ALLOWANCE OF THE WRIT

Title 35, United States Code, section 103 is fundamental to the patent system. This section of title 35 is critically involved in most patent lawsuits and in most patent applications that are filed. It is imperative that the law be as clear as possible with regard to the meaning and interpretation given to section 103. It is believed that the United States Court of Customs and Patent Appeals in deciding the case below has failed to apply the proper standards

in determining whether Dr. Jansen's preparation is patentable. It is believed that the law applied in the present case is inconsistent with the law applied in this Court's decision in *United States v. Adams,* 383 U.S. 39, 148 USPQ 479, (1966).

In the Adams case, this Court held that an invention directed to a combination of ingredients can be patentable even though each of the ingredients had been previously used in the same art. The Court there focused upon the improved results of the novel combination of Adams. Moreover, the response Dr. Jansen received from the Food and Drug Administration and others was not unlike the response Adams received when he first tried to gain approval for his invention, *United States v. Adams,* 383 U.S. at 43, 148 USPQ at 480:

> Less than a month after filing for his patent, Adams brought his discovery to the attention of the Army and Navy. Arrangements were quickly made for demonstrations before the experts of the United States Army Signal Corps. The Signal Corps scientists who observed the demonstrations and who conducted further tests themselves did not believe the battery was workable. Almost a year later, in December 1942, Dr. George Vinal, an eminent government expert with the National Bureau of Standards, still expressed doubts. He felt that Adams was making "unusually large claims" for "high watt hour output per unit weight," and he found "far from convincing" the graphical data submitted by the inventor showing the battery's constant voltage and capacity characteristics. He recommended, "Until the inventor can present more convincing data about the performance of his [battery] cell, I see no reason to consider it further."

The Constitutional standard for patentability is, of course, ultimately determined by this Court. The language of the Constitution authorizes patents to be granted to

"promote the progress" of the useful arts. It seems elementary that progress in the useful arts can only be determined by comparison of the results obtained with a new formulation to the results obtained with that which had gone before. To analyze an invention in a vacuum without comparison of the results obtained with it to results obtained with products previously marketed is to ignore the one of the most useful measures for determining progress within the useful arts. Christian J. Jansen, Jr. has attempted to have factual determinations made by the Patent and Trademark Office Board of Appeals and by the United States Court of Customs and Patent Appeals relating to results achieved with products marketed prior to Dr. Jansen's invention in comparison to the results achieved through the use of Dr. Jansen's novel preparation. The Board of Appeals in its decision on reconsideration stated as follows (Appendix, *infra* p. A-9):

> "We understand appellant's insistance that a composition containing the specified dosages of vitamin B_{12} and folic acid and that the administration of such dosages 'eliminate needless sickness and death, and reduce the cost of medical care' . . ., despite adverse criticism and condemnation. However, this running controversy between appellant and 'the entire scientific and medical community' . . . does not serve to establish the unobviousness of the claimed subject matter."

The Court of Customs and Patent Appeals completely sidestepped appellant's factual presentation concerning the improved safety of Dr. Jansen's product as compared with the prior art products and stated as follows (Appendix, *infra* p. A-16):

> "Appellant asserts a theory concerning the manner in which the claimed invention and method effectively treat undifferentiated anemia. We express no view on the merit of that theory."

Dr. Jansen's invention is the first *safe* vitamin preparation which contains sufficient folic acid to prevent folic acid deficiency. The prior art is replete with examples of vitamin preparations which either contain insufficient amounts of folic acid to insure prevention of folic acid deficiency or which have so much folic acid that the danger of masking of vitamin B_{12} deficiency is present.

It appears to petitioner that the decision of obviousness within the meaning of section 103 by the Court below could be considered to imply that the companies manufacturing the numerous folic-acid-containing products in the prior art have obviously known how to modify their formulations by a simple change in formulation to make them safe but rather they have preferred to market dangerous products and accompany those products with warning labels warning of the dangers, or alternatively have preferred to market products which have such an insufficient amount of folic acid that they do not insure prevention of folic acid deficiency. Petitioner would prefer to believe that his safe and effective preparation is unobvious to persons skilled in the art rather than to infer that the drug industry has such little concern for the risks of sickness and death associated with the products which it distributes.

It is believed that the decision of the United States Court of Customs and Patent Appeals is clearly at variance with the standards set forth by the United States Supreme Court in *Graham v. John Deere Co.*, 383 U.S. 1 at 17, 148 USPQ 459 at 467 (1966):

> "Under § 103, the scope and content of the prior art are to be determined; differences between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in the pertinent art resolved Against this background, the obviousness or non-obviousness of the subject matter is determined. Such secondary considerations as commercial success, long-felt but unsolved needs, failure of others, etc., might be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented. As indicia of obviousness or non-obviousness, these inquiries may have relevancy."

It is submitted that the United States Court of Customs and Patent Appeals has an obligation to consider the improved results obtained by the petitioner's preparation as compared to the preparations in the prior art. The evidence of improved safety submitted by petitioner in the Patent and Trademark Office should have been considered in determining the question of patentability under Section 103.

The large number of products presently marketed which are either dangerous or ineffective in regard to the folic acid content are believed to be persuasive evidence which needs to be considered. It is apparent to petitioner that he is the first and only advocate of a formulation of the type disclosed in his patent application. Not one example has been put forth by the Patent and Trademark Office of another oral folic-acid-containing product which overcomes the double edged problem of too much folic acid causing masking or too little folic acid allowing folic acid deficiency to occur. The fact that the pharmaceutical industry continues to manufacture products which are either inadequate or dangerous should have considerable relevance to the question of obviousness.

An affidavit of Christian Jansen filed in the Patent and Trademark Office states as follows:

> "7. I have monitored and extensively studied problems of anemia at Marion County General Hospital on 53 patients, most of whom were pernicious anemia patients; and the case histories of a few of these patients are attached as Exhibits B-0 to B-7;"

"9. I have never observed a case, nor am I aware of any case, in which the compositions of my invention have not been fully safe and fully effective in the treatment of either vitamin B_{12} deficiency anemia or folic acid deficiency or both;"

"12. I have observed many examples, such as those of the attached Exhibits, in which compositions of my invention have been used with complete safety and effectiveness in humans in preventing or curing anemia caused by either folic acid deficiency or vitamin B_{12} deficiency."

"13. I have directed research related to and extensively studied problems of anemia on at least fifty patients additional to those referred to in paragraph 7; and the case histories of a few of these patients are attached as Exhibits B-8 to B-13." (R-40, 41)

It is believed that this affidavit evidence should have been considered by the Patent and Trademark Office and by the United States Court of Customs and Patent Appeals. It is further believed that if this evidence had been properly considered along with the other evidence of record, that a conclusion that the claimed invention was unobvious would have been drawn.

In *Graham v. John Deere Co.*, 383 U.S. at 12, 148 USPQ at 464, this Court reaffirmed its adherence to the formulation of general conditions of patentability which this Court made in 1850 in *Hotchkiss v. Greenwood*, 11 How. 248, and stated:

"In practice, Hotchkiss has required a comparison between the subject matter of the patent, or patent application, and the background skill of the calling. It has been from this comparison that patentability was in each case determined."

This Court in *Graham*, 383 U.S. at 18, 148 USPQ at 467, made reference to a law review article, *Subtests of "Non-obviousness*, 112 U. Pa. L. Rev. 1169 (1964). This article treats various approaches to determinations of obviousness and states, p. 1172:

"The driving force behind innovation is the need for the improvement of existing technology. A defect in a product or process spurs the businessman to deploy resources for discovering a solution. High production costs, undesirable side effects from the use of a product, or a limited period of usefulness are typical of defects which will stimulate research. Existence of the defect creates a demand for its correction, and it is reasonable to infer that the defect would not persist were the solution "obvious."

Petitioner presented evidence in the Patent and Trademark Office of clinical tests proving the safety of his claimed invention with the very individuals who had demonstrated difficulty in absorbing vitamin B_{12} and who would be expected to have developed permanent neurological damage or died if they merely took a product of the prior art. The Board of Appeals of the Patent Office refused to consider this evidence as affecting the question of obviousness, and the United States Court of Customs and Patent Appeals followed suit. It is submitted that this type of evidence must be considered to properly evaluate patentability under the requirements of the United States Constitution and under the requirements of 35 U.S.C. § 103.

CONCLUSION

It is respectfully submitted that Certiorari should be granted as to each of the questions presented herein for review. The Court below made a fundamental error in not considering the evidence of improved safety presented to the Patent and Trademark Office. It is inconsistent with the Constitutional and statutory standards and inconsistent with the decisions of this Court to ignore evidence of significantly improved results obtained by a novel invention in making a determination of patentability. The Court of Customs and Patent Appeals erred in its determination of patentability and obviousness under 35 U.S.C. § 103. And further, if the decision below is left standing, it would be detrimental to the patent system and detrimental to the goal of promoting the *progress* of the useful arts for which the patent system owes its existence.

The grant of this Petition for Writ of Certiorari is believed to be fully warranted.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I, John Cameron McNett, counsel for Petitioner, hereby certify that I have served nine copies of the foregoing Petition for Writ of Certiorari by depositing three copies of the same in the United States Mail, properly stamped and addressed, to each of the following:

C. Marshall Dann
Commissioner of Patents and Trademarks
Washington, D. C. 20231

Solicitor General
Department of Justice,
Washington, D. C. 20530

Joseph F. Nakamura
Solicitor
U.S. Patent and Trademark Office
Washington, D. C. 20231

This twentieth day of February, 1976.

John Cameron McNett

APPENDIX

APPENDIX A

MAILED

BOARD OF APPEALS

SEP 11 1974

U.S. PATENT OFFICE

Appeal No. 151-56

IN THE UNITED STATES PATENT OFFICE

BEFORE THE BOARD OF APPEALS

Ex parte Christian J. Jansen, Jr.

Application for Patent filed July 22, 1970, Serial No. 57,302. Hematinic-Vitamin Preparation.

Woodard, Weikart, Emhardt and Naughton for appellant.

Before Magil and Schneider, Examiners-in-Chief, and Milestone, Acting Examiner-in-Chief.

Magil, Examiner-in-Chief.

This is an appeal from the final rejection of claims 1 through 11, all the claims now in the case.

Claims 1 and 11 are illustrative of the appealed claims and read as follows:

1. In an improved oral multifactor hematinic vitamin preparation which contains vitamin B_{12} and folic acid, the improvement which comprises having at least 0.1 milligram of vitamin B_{12} and at least 0.1 milligram of folic acid, in an approximate one to one ratio.

11. A method of treating and preventing anemia in humans which comprises administering a daily oral dosage of a vitamin preparation containing at least .5 mg. of vitamin B_{12} and at least .5 mg. of folic acid, whereby anemia can safely be treated orally without determining whether it is caused by folic acid deficiency or by vitamin B_{12} deficiency.

Claims 2 through 10 are all composition claims. Claim 2, dependent on claim 1, places an upper limit of 1 milligram on each of the components. Claims 3 through 7 are specific formulations including other vitamins and, in the case of claims 5 and 7, elemental iron. Claim 8 specifies the same two components as claim 1 but does not require a "one to one ratio." Claims 9 and 10 require 0.5 mg. of each of the two ingredients, with the last of these claims adding elemental iron. Classified somewhat differently, claims 1, 2, and 8 include as little as 0.1 mg. of folic acid and 0.1 mg. vitamin B_{12}, and claims 8 and 11 do not require that these two components be present in a "one to one ratio."

The references cited by the Examiner are:

Jurist	2,748,054	May 29, 1956
Sahyun	2,804,423	Aug. 27, 1957

Merck Index, 8th Edition (1968) pages 105, 455, 467-468, 729, 892, 918-919, 1036-1037, 1112-1113.

Physicians' Desk Refeernce (PDR) (1968), pages 738, 915, 1084, 1104, 1129.

Waife et al., *Annals of Internal Medicine,* Vol. 58, No. 5 (May 1963), pages 810-816.

We add pages 752, 811, and 812 to the Examiner's citation of Physicians' Desk Reference (PDR) because the Peritinic and Zentinic preparations described on those pages correspond generally to the "widely distributed formulation" described on page 5A of appellant's specification. Zentinic is referred to on pages 9 and 10 of appellant's principal brief.

All the claims have been rejected under 35 U.S.C. 101 "as being based on a lack of demonstrated utility that the claimed compositions and methods are safe and effective for the treatment of anemia in humans." This rejection is based on a letter from an official of the Food and Drug Administration to appellant, dated April 1, 1971. Said letter was submitted by appellant as an exhibit attached to his first amendment (Amendment A, Paper No. 3, filed November 8, 1971).

Our decision on the aforementioned rejection is governed by the case of *In re* Anthony, 56 CCPA 1443, 414 F.2d 1383, 162 USPQ 594. As in the cited case, the FDA has not here made an unequivocal finding that the claimed composition is totally unsafe in all circumstances of contemplated use. It is not within our jurisdiction to determine or to enforce the distribution system (over-the-counter or by-prescription-only) or mode of administration of pharmaceutical products. For all that we know, the FDA may ultimately approve prescription distribution of the claimed composition for particular conditions (*e.g.,* vitamin B_{12} deficiency coexisting with folic acid deficiency) with suitable precautions and monitoring after a new drug application with satisfactory proof. These are the functions of the FDA, and *our holding that the claims cannot be rejected under 35 U.S.C. 101 is not to be regarded as approval of all or any particular usage of the claimed composition.* Accordingly, we reverse the rejection under 35 U.S.C. 101.

All the appealed claims have been "rejected under 35 USC 112, second paragraph, as failing to particularly point out and distinctly claim the invention." However, none of the reasons stated by the Examiner are applicable to claims 2 and 9. Accordingly, this rejection must be reversed as to these two claims.

Claims 1, 8, and 11 are held by the Examiner to be indefinite because "at least" fixes no upper limit. We will not sustain the Examiner on this point because appellant's asserted contribution does not reside in determining the upper limits of administration of vitamin B_{12} and folic acid. According to the appealed claims, a therapeutic dose of each of these substances is assured and, in accordance with conventional knowledge in the art, a toxic dose would be avoided.

The Examiner holds claims 3 through 7 to be indefinite because of the parenthetical vitamin designation following the chemical name. He recognizes that the two terms are synonymous and he states that the parenthetical term is redundant. We agree with the appellant that no indefiniteness under 35 U.S.C. 112 results from the parenthetical vitamin identification. Assuming that excessive redundancy is objectionable, yet it appears from the PDR cited by the Examiner that dual identification is commonly employed in the vitamin field.

Claims 5 and 7 are held to be indefinite in the expression "elemental iron." This expression is also found in claim 10. It is quite evident that appellant's composition does not contain "elemental iron" but, rather, iron in the form of a salt (ferrous fumarate). This rejection is not contested by appellant and, inasmuch as it is clearly correct, it will be affirmed.

Finally, the Examiner holds claim 11 to be indefinite and too broad in "anemia" in the initial portion of the claim and indefinite, functional, and lacking adequate support in the "whereby" clause of the claim. We will not sustain this rejection. The condition for which the claimed method is employed is clear from the language of the claim as a whole. The "whereby" clause of the claim is adequately supported by the last two sentences on page 7 of appellant's specification.

In summation, the rejection under 35 U.S.C. 112 is affirmed as to claims 5, 7, and 10 but is reversed as to claims 1 through 4, 6, 8, 9, and 11.

All the claims have been "rejected under 35 USC 103 as being obvious over Merck in view of PDR, Jurist and Sahyun."

There is no dispute concerning the teachings of the cited references. Appellant recognizes that hematinic vitamin compositions have been prepared and used containing vitamin B_{12} and folic acid, as well as the other vitamins and iron of the more specific claims. Appellant's contribution to the art resides, according to pages 10 and 11 of the principal brief, in providing at least 0.1 mg. (100 mcg.) of each of vitamin B_{12} and folic acid, preferably 0.5 mg. (500 mcg.) of each. No separate argument is presented with respect to the other vitamins and iron of the more limited claims. According to appellant, use of his preparation eliminates the need for differentiating vitamin B_{12} deficiency from folic acid deficiency and the need for administering vitamin B_{12} parenterally and also avoids the dangers of error in diagnosis or masking effect.

Resolution of the issue of obviousness is simplified by appellant's acknowledgment on pages 12 and 13 of his principal brief that folic acid and vitamin B_{12} have been

individually orally administered in dosages of the order here claimed, by reference to FDA regulations and two cited publications. The *Waife et al.* publication, coauthored by appellant, also deals with oral administration of vitamin B_{12} in amounts corresponding to the appealed claims. With this state of the art, the only question which requires answering is whether it would be unobvious to formulate and use a composition containing *both* folic acid and vitamin B_{12} in the recognized therapeutic dosages. Our answer to this question is in the negative, despite appellant's vigorous arguments to the contrary, including his additional citation of a publication after the hearing on this appeal.

As we view appellant's asserted contribution, he has taken a "shotgun" approach to control of anemia, concurrently employing two recognized agents in known amounts for respective deficiencies. We do not use the word "shotgun" as a derogatory adjective, but merely as a convenient descriptive term. We refrain from becoming involved in the medical controversy over the rationality of the shotgun approach. We realize that some condemn the shotgun technique in that it encourages slovenly diagnosis and may result in dangerous "overkill." The contrary argument is that if the shotgun system is not dangerous, no harm is done in administering a broad spectrum of combined therapeutic agents. Our only concern is whether a shotgun composition is obvious rather than whether some practioners would condemn such a composition.

The essence of appellant's position is that because combination therapy is viewed with disfavor by some, it must be unobvious to formulate a combination therapeutic preparation. We cannot agree with appellant's conclusion, despite his emphasis on the premise.

As for the alleged benefits of appellant's composition, we can perceive nothing unexpected. It is entirely expected that a combination preparation may be used for an undifferentiated disorder. As for oral administration of vitamin B_{12} *vis-á-vis* parental administration, the literature cited in the first full paragraph on page 13 of appellant's principal brief indicates that the effectiveness of oral administration was recognized "as long ago as 1954."

In passing, we find it difficult to distinguish claims 1, 2, and 8 ("at least 0.1 milligram of vitamin B_{12} and at least 0.1 milligram of folic acid") from a double strength tablet of Peritinic (page 752 of PDR) or Zentinic (pages 811 and 812 of PDR), each commercial tablet containing 0.05 milligram of vitamin B_{12} and 0.05 milligram of folic acid, with the recommended dosage being 1 or 2 tablets daily. A double size tablet of Theragran Hematinic (page 1129 or PDR) is also pertinent to claim 8, which does not require a one to one ratio of vitamin B_{12} to folic acid.

In accordance with the foregoing discussion, the rejection of the appealed claims under 35 U.S.C. 103 will be sustained.

The decision of the Examiner is affirmed.

AFFIRMED

Woodard, Weikart, Emhardt
and Naughton
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Indianapolis, Indiana 46204

MAILED

BOARD OF APPEALS

OCT 30 1974

U. S. PATENT OFFICE

Appeal No. 151-56

IN THE UNITED STATES PATENT OFFICE

BEFORE THE BOARD OF APPEALS

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Woodard, Weikart, Emhardt and Naughton for appellant.

Before Magil, Schneider and Milestone, Examiners-in-Chief.

Magil, Examiner-in-Chief.

REQUEST FOR RECONSIDERATION AND REHEARING

Appellant requests reconsideration of our decision affirming the Examiner's rejection of claims 1 through 11 under 35 U.S.C. 103. No reconsideration is sought of

the affirmance of the rejection of claims 5, 7, and 10 under 35 U.S.C. 112.

The request for oral hearing is denied. Our heavy work load precludes oral reargument except under extraordinary circumstances, which are not here present. Appellant's position is well expressed in his written request for reconsideration, which we have carefully studied.

Appellant contends that we have not correctly understood his position and that we have not given adequate consideration to the circumstantial evidence of unobviousness.

We understand appellant's insistence that a composition containing the specified dosages of vitamin B_{12} and folic acid and that the administration of such dosages "eliminate needless sickness and death, and . . . reduce the cost of medical care" (page 2 of Request for Reconsideration), despite adverse criticism and condemnation. However, this running controversy between appellant and "the entire scientific and medical community" (page 4 of Request for Reconsideration) does not serve to establish the unobviousness of the claimed subject matter. As noted in our decision, vitamin B_{12} and folic acid have been included in a single composition and, with respect to dosages, the recommended two-tablet daily dose of Peritinic or Zentinic, corresponds to the terms of claims 1, 2, and 8, with a two-tablet daily dose of Teragran Hematinic also corresponding to the terms of claim 8.

Appellant would have us vindicate his position by holding the appealed subject matter unobvious, thereby proving his critics to be in error. We will not resolve this controversy. Appellant may be correct or his critics may be correct, but the claimed composition and method are clearly obvious from the teachings of the prior art. Our determin-

ation of obviousness is based on a study of the available art, and not on whether one practitioner would apply the label "safe and effective" while another practitioner would apply the label "unsafe and ineffective." We point out that lack of jurisdiction to determine safety and effectiveness led us to reverse the rejection under 35 U.S.C. 101.

We have considered the circumstantial evidence relied on by appellant but, again, this is but part of the picture of the controversy between appellant and those who espouse a contrary view. The condemnation of shotgun therapy does not render such therapy unobvious, the shotgun technique being shown in the art.

Reconsideration has been granted to the extent indicated by the foregoing discussion, but we decline to modify our decision in any respect.

DENIED

UNITED STATES COURT OF CUSTOMS AND PATENT APPEALS

IN THE MATTER OF THE APPLICATION OF CHRISTIAN J. JANSEN, JR.	) Patent Appeal No. 75-556.) Serial No. 57,302.

DECIDED: November 20, 1975

MARKEY, Chief Judge.

This appeal is from a decision of the Patent and Trademark Office Board of Appeals, adhered to on reconsideration, affirming the examiner's rejection of claims 1-4, 6, 8, 9 and 11 in application serial No. 57,302, filed July 22, 1970, for "Hematinic-Vitamin Preparation." We affirm.

The Invention

According to appellant's specification, an inadequate supply of either vitamin B_{12} (cyanocobalamin) or folic acid in the human diet results in fewer healthy red blood cells, producing the symptoms of anemia. Whether the condition is due to vitamin B_{12} deficiency or folic acid deficiency, or to a combination of the two, is difficult, expensive, and time consuming to determine. The determination has been deemed critical. Treatment of a vitamin B_{12} deficient patient with folic acid alone may result in an apparent cure or "masking" of continuing neurological effects of the deficiency and possible irreversible injury or death. Similarly, masking of a folic acid deficiency by administration of vitamin B_{12} alone may result in death, according to appellant's teachings.

Within this context appellant has proposed a solution whereby an oral hematinic multifactor vitamin preparation is administered, the preparation containing both vitamin B_{12} and folic acid, each in the amount of at least .1 milligram. Appealed claims 1 and 11 are illustrative:

> 1. In an improved oral multifactor hematinic vitamin preparation which contains vitamin B_{12} and folic acid, the improvement which comprises having at least 0.1 milligram of vitamin B_{12} and at least 0.1 milligram of folic acid, in an approximate one to one ratio.
>
> 11. A method of treating and preventing anemia in humans which comprises administering a daily oral dosage of a vitamin preparation containing at least .5 mg. of vitamin B_{12} and at least .5 mg. of folic acid, whereby anemia can safely be treated orally without determining whether it is caused by folic acid deficiency or by vitamin B_{12} deficiency.

The Rejection

The references cited by the examiner are as follows:

Jurist	2,748,054	May 29, 1956
Sahyun	2,804,423	Aug. 27, 1957

Merck Index 105, 455, 467-68, 729, 892, 918-19, 1036-37, 1112-13 (8th ed. 1968)

Physicians' Desk Reference (PDR) 738, 915, 1084, 1104, 1129, (1968)

Waife et al., *Oral Vitamin B_{12} without Intrinsic Factor,* 58 *Annals of Internal Med.* 810-16 (1963).

The board added "pages 752, 811, and 812 to the Examiner's citation of Physicians' Desk Reference (PDR)," noting that the Peritinic and Zentinic preparations described therein correspond generally to certain

"widely distributed formulation[s]" alluded to in appellant's specification.

What the prior art teaches is not in dispute. Appellant has admitted that it is well known to treat a patient having folic acid deficiency with folic acid alone in the amounts claimed. It is also well known to administer folic acid in an oral preparation. The oral administration of vitamin B_{12} alone in the amounts claimed is disclosed in the Waife et al. reference, coauthored by appellant. Oral preaprations containing both vitamin B_{12} and folic acid are also known, although such combination preparations do not contain the amounts claimed by appellant. Zentinic and Peritinic, for instance, are commercially available oral multifactor hematinic vitamin preparations containing .05 milligram of folic acid and .05 milligram of vitamin B_{12}, exactly half the minimum recommended dosage claimed by appellant.

The board had the following comments relative to appellant's asserted contribution, which it referred to as a "shotgun approach" to the control of undifferentiated anemia:

> We refrain from becoming involved in the medical controversy over the rationality of the shotgun approach. We realize that sone condemn the shotgun technique in that it encourages slovenly diagnosis and may result in dangerous "overkill." The contrary argument is that if the shotgun system is not dangerous, no harm is done in administering a broad spectrum of combined therapeutic agents. Our only concern is whether a shotgun composition is obvious rather than whether some practitioners would condemn such a composition.
>
> The essence of appellant's position is that because combination thereapy is viewed with disfavor by some, it must be unobvious to formulate a combination therapeutic preparation. We cannot agree with appellant's conclusion, despite his emphasis on the premise.

The board perceived "nothing unexpected" in appellant's composition, noting that it would be "entirely expected that a combination preparation may be used for an undifferentiated disorder." Moreover, it was determined that appellant's claims, specifying "at least 0.1 milligram of vitamin B_{12} and at least 0.1 milligram of folic acid," were difficult to distinguish from "a double strength tablet" of Zentinic or Peritinic. It was further found that a "double strength tablet" of Theragran Hematinic, which contains .05 milligram of vitamin B_{12} and .5 milligram of folic acid, would be pertinent to claim 8, whcih does not require a one-to-one ratio of vitamin B_{12} to folic acid. On reconsideration the board clarified its position somewhat by commenting:

> As noted in our decision, vitamin B_{12} and folic acid have been included in a single composition and, with respect to dosages, the recommended two-tablet daily dose of Peritinic or Zentinic, corresponds to the terms of claims 1, 2, and 8, with a two-tablet daily dose of Theragran Hematinic also corresponding to the terms of claim 8.

OPINION

We agree with the board that it would have been obvious to formulate and use a composition containing both folic acid and vitamin B_{12} in the recognized individual therapeutic dosages.

Appellant's position is that he has solved the problem of treating anemia in an unobvious way. Appellant relies upon evidence, also considered by the board, tending to show that some or perhaps even most persons having ordinary skill in the art would regard the claimed preparation as unsafe for treating certain types of anemia. A letter from Marvin Seife, M.D., Acting Director, Office of Scientific Evaluation, Bureau of Drugs, Food and Drug Administration stated:

> Your views on the safety and efficacy of your proposed product are not shared by the preponderance of contemporary scientific medical opinion.

Dr. Seife's letter quoted from a medical textbook:*

> It is therefore incumbent on the physician *never* to prescribe a multi-vitamin preparation containing more than .1 mg. of folic acid per daily dose unless he is reasonably sure that the patient does not have vitamin B_{12} deficiency.

A similar statement, apparently reflecting the opinion of the American Medical Association, is expressed in *AMA Drug Evaluations* 61 (1st ed. 1971):

> Combination therapy is indicated only when it can be clearly demonstrated that one type of anemia is superimposed upon another. Even under these circumstances, a combination of *the specific agents lacking in the particular anemias diagnosed are the only agents that should be used to treat the anemias.* Not only is avoidance of mixtures superior therapy from the standpoint of good medical practice, but also it may be absolutely necessary because the preferred route of administration of two different therapeutic agents may be entirely different. For example, an iron deficiency anemia superimposed on a pernicious anemia requires both iron and cyanocobalamin for treatment. However, the oral route is preferred for administering iron, whereas cyanocobalamin should be given by intramuscular or deep subcutaneous injection for best results.

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* Goodman & Gilman, *The Pharmacological Basis of Therapeutics*, 1440 (4th ed. 1970).

Appellant raises an unnecessary issue in arguing that the board has jurisdiction to consider opinions of the Food and Drug Administration and others concerning the safety and effectiveness of the claimed composition insofar as such opinions may relate to the question of obviousness under section 103, citing *In re Anthony*, 56 CCPA 1443, 414 F.2d 1383, 162 USPQ 594 (1969). The board properly cited *In re Anthony* as authority for its reversal of a rejection under 35 USC 101 and thereafter proceeded, in its review of the rejection under 35 USC 103, to consider fully the opinion evidence respecting safety submitted by appellant. Nothing in *In re Anthony* militates against jurisdiction of the board to consider such evidence in relation to the question of obviousness. The board determined, however, that such evidence was not persuasive of unobviousness in the claimed subject matter. We agree with that determination.

Whether members of the medical community agree or disagree with appellant's "shotgun approach" to treating undifferentiated anemia cannot control the determination of whether appellant's claimed combination product and method would have been unobvious to a person having ordinary skill in the art. The prior art is replete with examples of commercially available hematinic vitamin preparations containing combinations of vitamin B_{12} and folic acid. Hence, there is nothing new or unobvious in the combination per se. Neither is there anything new or unobvious about the individual dosage levels for vitamin B_{12} and folic acid employed by appellant.

Appellant asserts a theory concerning the manner in which the claimed composition and method effectively treat undifferentiated anemia. We express no view on the merit of that theory. Appellant's theory, however, cannot remove the effect of the prior art, which establishes that the

claimed composition and method would have been obvious to one of ordinary skill in the art.

Accordingly, the decision of the Patent and Trademark Office is *affirmed.*

AFFIRMED

PA 75-556